REMARKS

Claims 1, 70-77, 81-89, 91 and 93-138 are pending in this application. Claims 81-86 and 109-138 are withdrawn by the examiner. Claims 78-80, 90 and 92 are cancelled without prejudice or disclaimer. Claims 1, 70-77, 87-89, 91 and 93-108 are currently under examination. Claims 1, 70-77, 87-89, 91 and 93-96, 99, and 102-108 are amended for clarity as discussed herein. Therefore, no new matter is introduced. The Office Action is discussed below:

Objections to the Specification:

On pages 2-3 of the Office Action, the examiner states that there were two abstracts submitted on January 18, 2005. In response, as suggested by the examiner, applicants herewith submit one abstract, which replaces the abstracts submitted earlier. The new abstract specifies that the invention discloses a constitutive promoter from the Taro bacilliform virus (TaBV).

Also, as suggested by the examiner, the title of the application is replaced to read as "TaBV transcriptional control elements, chimeric constructs and uses therefor."

Further, applicants herewith submit a substitute specification to replace the abstract and the title, as clarified above, and to correct the informalities related to the blank areas.

Withdrawal of the objections to the specification is therefore requested.

Objections to the Claims:

On pages 3-5 of the Office Action, the examiner has objected to claims 73-77, 99, and 102-108 under 37 CFR 1.75(c), allegedly as being of improper dependent form for failing to further limit the subject matter of a previous claim, technical errors and/or informalities.

Claims 73 and 74 are amended to recite a plant, as suggested by the examiner. Claims 75-76 are amended in accordance with the amended claim 74.

Claim 77 is amended to correct the informalities.

Claims 99 is amended to recite "a nucleic acid sequence encoding a targeting sequence" in view of the examiner's comments on page 5, lines 1-3, of the Office Action.

Claim 102 is amended to recite a host cell transformed with a construct, and as suggested by the examiner. Claims 103-108 are amended in accordance with the amended claim 102.

Indefiniteness Rejection:

On pages 5-8 of the Office Action, the examiner has rejected claims 1, 70-77, 87-89, 91, and 93-108 under 35 U.S.C. 112, second paragraph, allegedly as being indefinite.

In particular, the examiner has objected to a number of the terms and phrases used in the claims as being unclear, which are listed as follows: "at least high stringency conditions"; "the nucleotide sequence"; "obtained from"; "operably linked to a foreign or endogenous DNA sequence to be transcribed"; "foreign"; "endogenous"; "aimed at down-regulating"; "a transcribed region that represents a molecule" and "represents". In response, applicants amend the claims for clarity as discussed herein.

Regarding the hybridization conditions recited in claims 1 and 70, applicants refer to the specification page 14, lines 21-28, page 20, lines 5-20, and page 24, line 33 to page 25 line 4, for example. For clarity, the claims are amended by deleting the term "at least".

In order to clarify the phrase "the nucleotide sequence" in claims 71-74, 77, 87, 89, and 91, the claims are amended to refer to specific sequences as suggested by the examiner. Claims 71 and 72 also are amended by replacing the term "obtained" with "derived" for clarity.

Claims 87-89, 93, 94 and 99 are amended by deleting the terms "foreign" and "endogenous" to clarify that the nucleotide sequence is operably linked to the DNA

sequence to be transcribed.

Additionally, the term "aimed at" in claim 95 is replaced by "for" and claim 96 is amended by replacing the term "represents" with "comprises".

Written Description Rejection:

On pages 8-11 of the Office Action, the examiner has rejected claims 73-76, 87-89, 91, and 93-108 under 35 U.S.C. 112, first paragraph, allegedly for failing to comply with the written description requirement. Specifically, the examiner alleges that the specification fails to describe a representative number of DNA molecules that hybridize to SEQ ID NO: 6, 7 or 8 or have 90% identity to SEQ ID NO: 6, 7 or 8 that have promoter activity.

Applicants respectfully disagree with the examiner and submit that the claims contain subject matter described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In this context, applicants refer the examiner to the dictates of the MPEP that:

> "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))."
>
> *See* MPEP §2163.02 (Rev. 6, September 2007 at 2100-185-186).

Applicants also refer to the specification, for example, pages 27-32, section 6.2

and related section 3.0, which clearly disclose and provide guidance to one skilled in the art for selecting promoter variants of the invention using techniques well known in the art and for producing the claimed chimeric DNA constructs.

In addition, applicants amend claims 1 and 70 to recite that "the DNA molecule having a nucleotide sequence of at least 300 nucleotides, wherein the nucleotide sequence has at least 95% sequence identity to the sequence set forth in SEQ ID NO:8" or "the nucleotide sequence hybridizes to the sequence set forth in SEQ ID NO:8 under high stringency conditions...." Examples of such molecules are disclosed in the specification, as agreed by the examiner, and additional variants can be obtained by one skilled in the art using the teaching from the specification, as clarified above.

As requested by the examiner on page 9, paragraph 2, of the Office Action, applicants state that the examiner's assumption is correct to the extent that the nucleic acid of SEQ ID N0:6 having 1190 bases is a promoter sequence, as described in the specification, and the Tas-1/TR described on Table 1 comprises a sequence as set forth in SEQ ID NO:6. The examiner's assumption also is correct to the extent that the clones designated as T600 comprise a sequence as set forth in SEQ ID NO:7 (598 bases in length) and clones designated as T500 comprise a sequence as set forth in SEQ ID NO:8 (529 bases in length).

In view of the above, applicants submit that the written description requirement has been met, accordingly, withdrawal of the rejection is solicited.

Enablement Rejection:

On pages 12-15 of the Office Action, the examiner has rejected claims 1, 70-77, 87-89, 91, and 93-108 under 35 U.S.C. 112, first paragraph, allegedly as being non-enabling, because the specification, while being enabling for an isolated DNA molecule comprising SEQ ID NO:8; and for a chimeric construct comprising said molecule, does not reasonably provide enablement for a DNA molecule comprising a nucleotide sequence that has at least 90% identity to SEQ ID NO:8 or that hybridizes to SEQ ID NO:8; or for a chimeric construct comprising said molecule.

According to the examiner, the claims are broadly drawn to a DNA molecule comprising a nucleotide sequence that has at least 90% identity to SEQ ID NO:6, 7, or 8 or that hybridizes to SEQ ID N0:6, 7, or 8; and to a construct comprising said molecule. The examiner states that the only DNA molecules that hybridize to SEQ ID NO:8 or have 90% identity to SEQ ID N0:8 that are taught to have promoter activity; are DNA molecules that comprise SEQ ID N0:8.

The examiner also states that the application does not teach any use for the DNA molecules other than to be used as promoters. Therefore, any DNA molecules that have 90% identity to SEQ ID N0:6, 7, or 8 or that hybridize to SEQ ID N0:6, 7, or 8 that are not effective as promoters in plants are not enabled by the instant specification.

According to the examiner, the claims are broadly drawn to a DNA molecule comprising a nucleotide sequence that has at least 90% identity to SEQ ID NOs: 6, 7, or 8 or that hybridises to SEQ ID NOs: 6, 7, or 8, and to a construct comprising the DNA molecule. The examiner states that the only DNA molecules that hybridise to SEQ ID NO: 8 or have 90% identity to SEQ ID NO: 8 that are taught in the specification to have promoter activity, are DNA molecules that comprise SEQ ID NO: 8. The examiner also states that the application does not teach any use for the DNA molecules other than to be used as promoters. Therefore, any DNA molecules that have 90% identity to SEQ ID NOs: 6, 7, or 8 or that hybridise to SEQ ID NOs: 6, 7, or 8 that are not effective as promoters in plants are not enabled by the instant specification.

Furthermore, the examiner asserts that there is a high degree of unpredictability in altering promoter sequences, and the claims are inclusive of sequences with insertions, deletions, and substitutions relative to the nucleic acid sequence within the specification that has been shown to have promoter activity. Thus, the examiner believes that, given the breadth of the claims, the lack of guidance and working examples, the unpredictability in the art, and the state-of-the-art, undue experimentation would be required to make and use the claimed invention. Therefore, the invention is not enabled through the broad scope of the claims.

Applicants respectfully disagree with the examiner and refer to above clarifications that the specification discloses and provides guidance to one skilled in the

art for obtaining the claimed promoter variants using routine techniques that are well known in the art. See specification, for example, pages 27-32, section 6.2 and related section 3.0.

In this context applicants refer the examiner to dictates of the MPEP that:

> "Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)."
>
> *See* MPEP §2164.01 (Rev. 6, September 2007 at 2100-193).

Applicants also submit that an undue experimentation would not be required to make and use the claimed invention in light of the methods described in the specification and known in the art. Regarding the examiner's concern of the lack of guidance and working examples, applicants refer to the fact that the:

> "...experimentation may be complex <u>does not necessarily make it undue</u>, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).
>
> *See* MPEP §2164.01 (Rev. 6, September 2007 at 2100-194).

Applicants also refer that working examples are not required in a patent application, and the mere absence of such examples is not sufficient to support a written description rejection. *Falkner v. Inglis*, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006).

As discussed above, based on the teaching of the specification, it is apparent that one skilled in the art would be able to make claimed promoters, cells and the chimeric DNA constructs (see specification pages 22 through 32, for example). Activity

of such promoters also can be determined by the examples as set forth in the specification (see Examples 8-16, on pages 51-57, for example. Therefore, the claimed inventions are supported by an enabling disclosure.

Regarding additional working examples, applicants submit that working examples are not required to satisfy the enablement requirement and refer that:

> "Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved....
>
> The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970)."
>
> *See* MPEP §2164.02 (Rev. 6, September 2007 at 2100-196).

However, applicants amend claims 1 and 70 to recite a promoter comprising an isolated DNA molecule having a nucleotide sequence that has at least 95% sequence identity or hybridizes to the sequence set forth in SEQ ID NO:8 under high stringency conditions (see specification pages 24, line 33 to page 25 line 4, for example). In view of the above clarifications and amendments, applicants submit that the claimed inventions are supported by an enabling disclosure. Accordingly, withdrawal of the enablement rejection is solicited.

Anticipation Rejection:

On pages 15-18 of the Office Action, the examiner has rejected claims 1, 70-77, 87-89, 91, and 93-108 under 35 U.S.C. 102(b) allegedly as being anticipated by Schenk *et al.* (WO 99/00492). On pages 18-20 of the Office Action, the examiner also has rejected claims 1, 70-77, 87-89, 91, and 93-108 under 35 U.S.C. 102(a) and 35 USC 102 (e) allegedly as being anticipated by Schenk *et al.* (US Patent No. 6,391,639, which also is published as WO 99/00492). Applicants respectfully disagree and invite the examiner to consider the MPEP, which states:

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) ..... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).
>
> *See* MPEP §2131 (Rev. 6, September 2007 at 2100-67).

The examiner states that Schenk *et al.* disclose a promoter from the banana streak badnavirus and they teach DNA that hybridizes to this promoter (refers to page 2, line 31). Allegedly, the promoter has a region of high homology with SEQ ID NO: 8 of the instant application. The examiner has provided a sequence alignment between a region of SEQ ID NO: 8 and the promoter sequence disclosed in WO 99/00492. The alleged sequence appears to have a similarity of approximately 75%. In response, applicants point out that the instant claims recite a sequence having at least 95% sequence identity. Therefore, the Schenk *et al.* do not disclose the claimed inventions.

The examiner alleges (see page 19 of the Office Action) that because the "at least high stringency conditions" have not been defined, the promoter taught by Schenk *et al.,* would also hybridize to SEQ ID NO: 6 and 7 under some stringency conditions, because it is an inherent property of DNA to hybridize to other DNA. Regarding the disclosure of "high stringency conditions", applicants refer to the specification page 14, lines 21-28, page 20, lines 5-20, and page 24, line 33 to page 25 line 4, for example.

Applicants point out that the sequence alignment provided by the examiner involves only 125 nucleotides. In order to expedite the prosecution and to further distinguish the claimed invention from the cited references, claims 1 and 70 are amended to recite a promoter comprising an isolated DNA molecule having a nucleotide sequence of at least 300 nucleotides that has at least 95% sequence identity or that hybridizes to the sequence set forth in SEQ ID NO:8 under high stringency conditions (see specification, for example, page 13, lines 28-30, for the length of the

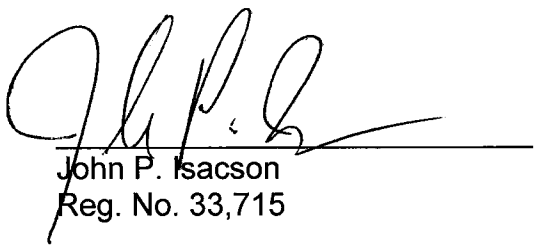
sequences; page 24, line 33 to page 25 line 4, for the high stringency conditions). Applicants point out that Schenk *et al.* neither teach nor suggest a promoter with a region that is at least 300 nucleotides in length having at least 95% sequence identity with SEQ ID NO: 8 of the present application.

In view of the above clarifications and amendments, applicants submit that the claimed invention is different from what is disclosed in Schenk *et al.* In addition, Schenk *et al.* do not disclose each and every element as set forth in the claimed invention. Therefore, Schenk *et al.* do not anticipate the claimed invention. Accordingly, withdrawal of the anticipation rejection is requested.

REMARKS

Applicants submit that claims 1, 70-77, 87-89, 91 and 93-108 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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